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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,738	04/30/2001	George Jackowski	2132.040	3448

21917 7590 12/09/2002

MCHALE & SLAVIN  
4440 PGA BLVD  
SUITE 402  
PALM BEACH GARDENS, FL 33410

[REDACTED] EXAMINER

COOK, LISA V

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1641

DATE MAILED: 12/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/845,738	JACKOWSKI ET AL.	
	Examiner Lisa V. Cook	Art Unit 1641	
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>			
<b>Period for Reply</b>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>18 November 2002</u> .			
2a) <input type="checkbox"/> This action is <b>FINAL</b> .      2b) <input type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-35</u> is/are pending in the application.			
4a) Of the above claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input type="checkbox"/> Claim(s) _____ is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input checked="" type="checkbox"/> Claim(s) <u>1-35</u> are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .		6) <input type="checkbox"/> Other: _____ .	

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2 are drawn to a biopolymer having ITHRIHWESASLL (SEQ ID NO: 1), classified in class 530, subclass 300 or class 530, subclass 350 for example.
  - II. Claims 3-9, 18-28 and 33-35 are drawn to methods and kits which not only detect SEQ ID NO: 1, further requiring a correlation to disease state, diagnosing, therapeutic avenues, an/or risk assessment, classified in class 436, subclass 518 and class 424, subclass 93.1 for example.
  - III. Claims 10-17 are drawn to kit for merely detecting SEQ ID NO: 1, classified in class 422, subclass 61 for example.
  - IV. Claims 29-32 are drawn to antibodies that bind SEQ ID NO: 1, classified in class 530, subclass 387.1/387.2 and class 424, subclass 130.1 for example.
2. The inventions are distinct, each from the other because of the following reasons:
  - A. Inventions **I and IV** are drawn to tow disclosed patentably distinct inventions (compositions comprising materially different limitations). Group I is directed to a biopolymer while Group IV is directed to antibodies with specificity for the biopolymer. The two products are independent and require different searches. These separate products/compositions bear distinct structural or biochemical properties. **Therefore, each disclosed patentably distinct composition is considered a separate invention.**

B. The method/kit inventions of Group **II** and **III** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventive methods/kits are patentably distinct. Group II *merely detects* Seq Id No: 1, while Group III is drawn to methods/kits that not only detect Seq Id No: 1 but further correlates the detection to disease state assessment, product regulation, and therapeutic evaluations. The additional correlation is not required in the kit of invention II. Therefore the methods/kits utilize different reagents and have different method steps (different modes of operation/function/effects).

It is recognized that although the search for the inventions may overlap they are not totally co-extensive, where the search for one would fully encompass the search for the others. Because these inventions are distinct for the reasons given above and the search required for Inventions IV-IX are not mutually inclusive (i.e. the search for one invention is not required for the other inventions) restriction for examination purposes as indicated is proper.

C. Inventions (**I and IV**) and (**II and III**) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the products are materially different and can be used in any of the materially different processes/kits of invention II and III.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and **do not** represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO fax center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Lisa V. Cook  
Patent Examiner  
Art Unit 1641  
CM1-7B17  
12/4/02

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/1641